K112875

Blue Sky Bio, LLC

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SUITE 212
GRAYSLAKE, IL 60030
Tel: 718-376 0422
Fax: 888-234 3685
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JAN 27 2012

510(K) Summary

General Information

Classification Name:	Endosseous Implant
Common Name:	Prosthetic Dental Implant System
Trade Name:	Blue Sky Bio Dental Taper Hex Implant System
Submitter's Name:	Blue Sky Bio, LLC
Address:	888 E Belvidere Rd., Suite 212 Grayslake, IL 60030
Telephone:	847-548 8499
Fax:	847-548 8491
Contact:	Michele Vovolka
Date of Summary	**June 2011**

Device Description

The modification of the Blue Sky Bio Dental Implant System consists of root form dental implants of various lengths and associated abutment systems, which provide the clinician with cement retained , screw retained and overdenture-type restorative options. Modifications to the existing system do not introduce new issues of safety or efficacy. The implants and components are supplied sterile or not sterile and are labeled accordingly.

Intended Use

- Blue Sky Bio 3mm Double Hex implants are primarily intended for restoration of mandibular incisors and maxillary lateral incisors
- Blue Sky Bio 3mm Double Hex Dental Implant System is intended for implantation into the fully and partially edentulous ridge for the support of a dental prosthesis, and for single tooth replacement in the anterior area of the jaws
- Implants can be placed in immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.
- Multi-unit abutments for fixed restorations are to be used only for multiple splinted restorations.
- In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.
- Blue Sky Bio 3mm Double Hex Dental Implant System is compatible with Astra Osseospeed Narrow Dental Implant System.

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Technological Characteristic Comparison

Feature	Subject Device Blue Sky Bio 3mm Dental Implant System (Double Hex 3mm)	Predicate Device Astra Tech 3mm Dental Implant System K080396.
Material	CP Titanium Grade 4, Ti-6Al-4V	CP Titanium Grade 4
1 Stage/ 2 Stage	2 Stage	2 Stage
Surface	Blasted with resorbable medium, or Aluminum Oxide and acid etched	Blasted with titanium oxide and acid etched
Body Diameter (mm)	3 mm	3mm
Platform Diameter (mm)	3mm	3mm
Lengths (mm)	10, 11, 13, 15, 17 mm	11, 13, 15, 17 mm
External Screw Threads	Yes	Yes
Anti-rotational Feature	Internal Double Hex with taper,	Internal Double Hex with taper
Gamma Sterilized	Yes	Yes
Solid abutment	Yes	Yes
Two-Piece Screwed Abutment	Yes	Yes
Overdenture abutment	Yes	Yes
Instruments (surgical and restorative)	Yes	Yes
Angled Abutment	Yes Multiunit	Yes TiDesign
Single Unit	Yes	Yes
Multiple Unit	Yes	Yes

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Safety and Efficacy

The material, technology and facilities used to produce the modified Blue Sky Bio Dental Implant Systems are the same. Therefore it is substantially equivalent to other commercially available Dental Implant Systems including predicate devices Osseospeed Narrow Dental Implant System Astratech (K080396) and to Blue Sky Bio Dental Implant System (K073713)
The technical comparison charts list the primary technical aspects and specifications that are pertinent to Dental Implant Systems. The 3mm Blue Sky Bio dental implant system is as safe and effective as the predicate devices.

Non-Pyrogenic Statement

No claims are made that the products are non-pyrogenic.

Performance Tests

Compatibility tests with other systems according to Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document; Root-form Endosseous Dental Implants and Endosseous Dental Abutments: These tests were performed to assess compatibility with predicate devices. The tests showed that the new devices are compatible with predicate devices and the fit is adequate.

Fatigue testing for angled abutments and narrow diameter implants: This test has been conducted according to ISO 14801 for predicate devices. The new devices have the same wall thickness and equal or smaller angulation than the predicate devices and are therefore equivalent or stronger than the predicate devices.

Conclusion

The Blue Sky Bio Dental Implant system, subject to this submission and the predicate devices are believed to be substantially equivalent. The device constitutes a safe, reliable and effective medical device, meeting all declared requirements of its intended use and the device does not introduce new risks and does not present any adverse health effects or safety risks to patients when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Michele Vovolka
Correspondent
Blue Sky Bio, LLC
888 E Belvidere Road, Suite 212
Grayslake, Illinois 60030

JAN 2 7 2012

Re: K112875
Trade/Device Name: Blue Sky Bio Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: January 8, 2012
Received: January 19, 2012

Dear Ms. Vovolka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if Known): K112875

Device Name: Blue Sky Bio Dental Implant System

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- Blue Sky Bio 3mm Double Hex Dental Implants are compatible with Astra Osseospeed Narrow abutments.
- Blue Sky Bio 3mm Double Hex Abutments are compatible with Astra Osseospeed Narrow Implants.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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